

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan

MHRA-102482-PIP01-26

Scope of the Application

Active Substance(s)

Human rabies immune globulin

Condition(s)

Prevention of rabies infection

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Kamada Ireland Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Kamada Ireland Limited submitted to the licensing authority on 18/05/2026 10:03 BST an application for a Paediatric Investigation Plan

The procedure started on 19/05/2026 15:35 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-102482-PIP01-26

Of 27/08/2026 11:14 BST

On the adopted decision for Human rabies immune globulin (MHRA-102482-PIP01-26) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Human rabies immune globulin, Solution for injection , Intramuscular use .

This decision is addressed to Kamada Ireland Limited, Greenmount Industrial Estate, Greenmount Avenue , Dublin, IRELAND, D12 K883

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of rabies infection

2.2 Indication(s) targeted by the PIP:

Post-exposure prophylaxis of rabies infection in persons after exposure to scratches, bites or other injuries including mucous membrane contamination with infectious tissue, such as saliva, caused
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by a suspected rabid animal. Human rabies immunoglobulin must always be used in combination with a rabies vaccine.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

All subsets of the paediatric population from birth to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (KamRAB-004) Prospective, open-label, study to confirm safety and effectiveness of a human rabies immune globulin (HRIG) as part of post-exposure prophylaxis (PEP) in children from birth to less than 18 months of age.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/11/2019
Deferral of one or more studies contained in the paediatric investigation plan:	No

